NIEHS IRB
Bulletin#5

EXPLANATION OF NIH FORMS
& PRE-IRB SCIENTIFIC REVIEW OF PROTOCOLS

Completion of NIH 1195 (Initial Review) and NIH 1195-1 (Continuing Review) Protocol Cover Forms

In completing the NIH forms all categories must be checked off and signatures from appropriate individuals must be obtained before submission to the IRB for review.

Signatures and Designation of Associate Study Investigators

The latest versions of the forms for submission of IRB protocols (Initial Review form NIH-1195 AND Continuing Review form NIH-1195-1) now contain new signature lines and spaces to include information on a "***lead associate investigator***" where possible. Please note the following:

Accountable Investigator.

The Protocol Coordination Service Center (PCSC) at NIH now processes all "off-site" protocols (NIEHS is considered "off-site"), and they require submission of a ***complete*** NIH-1195, including the ***Accountable Investigator*** field. The requirement for submission of a complete NIH-1195 will ensure that accurate data is available in their database for tracking and reporting purposes. Therefore, ***if the Principal Investigator is also the Accountable Investigator, he/she is required to sign in <u>both</u> places on the NIH-1195.***

An ***Accountable Investigator*** is defined as a tenure or tenure-track investigator who is responsible and accountable for the scientific quality and the expenditure of resources for the conduct of a protocol. In some Institutes, that responsibility is carried by the Branch Chief or Department Head, whose signature is sufficient. Otherwise, the Accountable Investigator signs and forwards the NIH-1195 form and proposed protocol to the Branch Chief or Department Head. -- *Protomechanics*, 3rd edition, January 2000

You should determine with your Branch Chief whether or not you qualify as an ***Accountable Investigator***.

Lead Associate Investigator.

This is an optional category on the face sheet for new and continuing review clinical research protocols. A ***lead associate investigator*** is defined as an associate investigator who has played a leading role in the formulation, writing, and implementation of a clinical research protocol under the mentorship of the protocol's principal investigator. A

lead associate investigator may be a physician, a dentist, a student, a Ph.D., an RN, a member of the allied health professions, or a trainee. This designation was created by the Medical Executive Committee in order to allow for recognition of those individuals who have had an active role in the protocol's development but are precluded from being a principal investigator. This should be kept up to date as personnel changes occur.

Conflict of Interest and Disclosure of Royalties:

The following questions have been added to the form. If you have questions about these, please contact the Clinical Director.

Do any investigators have equity, consultative, or other financial relationship with a non-NIH source related to this protocol which might be considered a conflict of interest? If "yes" is answered, a statement of disclosure must be appended.

"Does the protocol involve a drug/device/product that may lead to you or to the NIH receiving payment and/or royalties?" If "yes" is answered, a statement of disclosure must be appended. The Medical Executive Committee endorsed addition of this question to facilitate reporting of potential conflict of interest activities by investigators.

Pre-IRB Scientific Review of Protocols

All protocols must have ***scientific review*** before coming to the IRB.

At NIEHS, once the PI, the Accountable Investigator, and the Branch Chief have signed a protocol, the protocol then goes to ***Pre-IRB Scientific Review*** (also called ***Internal Scientific Review***) before it can be considered by the IRB.

- For NIEHS Epidemiology Branch projects, this is typically done by the Branch, and this review is accepted by the Deputy Scientific Director.
- For all other NIEHS Labs and Branches, please contact the office of the Deputy Scientific Director, Dr. Schrader, regarding review and approval.

The IRB cannot review protocols that have not been previously approved by the Clinical Director and Deputy Scientific Director.